Clinical trial results:
A phase 2b, open-label study to evaluate the safety, tolerability, and immunogenicity of vaccine candidate BNT162b2 in immunocompromised participants >=2 years of age.

Summary

EudraCT number	2021-001290-23
Trial protocol	DE
Global end of trial date	23 July 2023

Results information

Result version number	v1 (current)
This version publication date	07 February 2024
First version publication date	07 February 2024

Trial information

Trial identification

Sponsor protocol code	C4591024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04895982
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002861-PIP02-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 August 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to describe the safety, tolerability and immune response to prophylactic BNT162b2 in immunocompromised subjects >=2 to >=18 years of age without serological or virological evidence of past Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV2) infection and with representative medical conditions. Representative conditions for subjects >=18 years of age included non-small cell lung cancer (NSCLC), chronic lymphocytic leukemia (CLL), haemodialysis treatment secondary to end-stage renal disease, or immunomodulator therapy for an autoimmune inflammatory disorder. Representative conditions for subjects >=2 to <18 years of age included those with autoimmune inflammatory disorders receiving immunomodulators, those who had undergone organ transplant and were receiving maintenance antirejection modulators, and those who had undergone bone marrow or stem cell transplant.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 October 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 46
Country: Number of subjects enrolled	Brazil: 25
Country: Number of subjects enrolled	United States: 50
Country: Number of subjects enrolled	Mexico: 3
Worldwide total number of subjects	124
EEA total number of subjects	46

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	102
Adolescents (12-17 years)	15
Adults (18-64 years)	5
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 124 subjects were enrolled in this study.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	2 to <5 Years with Immunomodulatory Therapy

Arm description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms BNT162b2 administered intramuscularly

Arm title	2 to < 5 Years with Solid Organ Transplant

Arm description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms BNT162b2 administered intramuscularly

Arm title	2 to < 5 Years with Stem Cell Transplant

Arm description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms BNT162b2 administered intramuscularly

Arm title	5 to <12 Years with Immunomodulatory Therapy

Arm description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms BNT162b2 administered intramuscularly

Arm title	5 to <12 Years with Solid Organ Transplant

Arm description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms BNT162b2 administered intramuscularly

Arm title	5 to <12 Years with Stem Cell Transplant

Arm description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms BNT162b2 administered intramuscularly

Arm title	12 to <18 Years with Immunomodulatory Therapy

Arm description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Arm title	12 to <18 Years with Solid Organ Transplant

Arm description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Arm title	12 to <18 Years with Stem Cell Transplant

Arm description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Arm title	>=18 Years with Immunomodulatory Therapy

Arm description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Arm title	>=18 Years with Non-Small Cell Lung Cancer

Arm description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Arm title	>= 18 Years with Haemodialysis

Arm description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

30 micrograms BNT162b2 administered intramuscularly

Number of subjects in period 1	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant
Started	9	15	13
Dose 1	9	15	13
Dose 2	9	15	12
Dose 3	9	15	11
Dose 4	7	13	6
Completed	7	12	6
Not completed	2	3	7
Refused further study procedures	-	-	1
Unspecified	-	-	1
Lost to follow-up	-	-	1
Withdrawal by parent/guardian	2	3	3
Protocol deviation	-	-	1
Withdrawal by subject	-	-	-

Number of subjects in period 1	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant
Started	19	24	22
Dose 1	19	24	22
Dose 2	19	24	22

Dose 3	17	24	22
Dose 4	14 [1]	20	17 [2]
Completed	16	20	18
Not completed	3	4	4
Refused further study procedures	-	-	-
Unspecified	1	-	-
Lost to follow-up	-	-	1
Withdrawal by parent/guardian	1	3	2
Protocol deviation	1	1	-
Withdrawal by subject	-	-	1

Number of subjects in period 1	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant
Started	7	1	7
Dose 1	7	1	7
Dose 2	7	1	7
Dose 3	7	1	6
Dose 4	5	1	3
Completed	5	0	3
Not completed	2	1	4
Refused further study procedures	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	1
Withdrawal by parent/guardian	1	-	3
Protocol deviation	-	1	-
Withdrawal by subject	1	-	-

Number of subjects in period 1	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis
Started	5	1	1
Dose 1	5	1	1
Dose 2	5	1	1
Dose 3	5	1	1
Dose 4	3	1	0
Completed	3	1	0
Not completed	2	0	1
Refused further study procedures	-	-	-
Unspecified	1	-	-
Lost to follow-up	-	-	-
Withdrawal by parent/guardian	-	-	-
Protocol deviation	-	-	-

Withdrawal by subject	1	-	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone includes only subjects who received doses. The study completion includes subjects who completed the study 6 months after Dose 3 (per protocol amendment 3) and subjects who completed the study 6 months after Dose 4 (per protocol amendment 4).

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone includes only subjects who received doses. The study completion includes subjects who completed the study 6 months after Dose 3 (per protocol amendment 3) and subjects who completed the study 6 months after Dose 4 (per protocol amendment 4).

Reporting groups

Reporting group title	2 to <5 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to < 5 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to < 5 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Non-Small Cell Lung Cancer

Reporting group description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>= 18 Years with Haemodialysis

Reporting group description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant
Number of subjects	9	15	13
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	9	15	13
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
median	3.0	4.0	3.0
full range (min-max)	2 to 4	2 to 5	2 to 4
Gender Categorical Units: Subjects			
Female	4	8	3
Male	5	7	10
Race Units: Subjects			
White	9	11	12
Black or African American	0	2	0
Asian	0	1	0
Multiracial	0	0	1
Not reported	0	1	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	1	1	4
Non-Hispanic/non-Latino	8	14	9
Not reported	0	0	0

Reporting group values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant
Number of subjects	19	24	22

Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	19	24	22
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
median	10.0	8.0	8.5
full range (min-max)	5 to 11	5 to 11	6 to 11
Gender Categorical Units: Subjects			
Female	12	9	5
Male	7	15	17
Race Units: Subjects			
White	17	21	19
Black or African American	1	0	3
Asian	0	1	0
Multiracial	0	1	0
Not reported	1	1	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	6	2	2
Non-Hispanic/non-Latino	13	22	19
Not reported	0	0	1

Reporting group values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant
Number of subjects	7	1	7
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	7	1	7
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0

Age Continuous Units: years			
median	13.0	14.0	12.0
full range (min-max)	12 to 16	14 to 14	12 to 15
Gender Categorical Units: Subjects			
Female	2	0	5
Male	5	1	2
Race Units: Subjects			
White	6	1	7
Black or African American	0	0	0
Asian	1	0	0
Multiracial	0	0	0
Not reported	0	0	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	3	0	1
Non-Hispanic/non-Latino	4	1	6
Not reported	0	0	0

Reporting group values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis
Number of subjects	5	1	1
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	1	1
From 65-84 years	2	0	0
85 years and over	0	0	0
Age Continuous Units: years			
median	39.0	40.0	62.0
full range (min-max)	31 to 73	40 to 40	62 to 62
Gender Categorical Units: Subjects			
Female	3	0	0
Male	2	1	1
Race Units: Subjects			
White	1	0	0
Black or African American	2	0	0
Asian	0	0	0
Multiracial	1	0	0

Not reported	1	0	1
American Indian or Alaska Native	0	1	0
Ethinicity Units: Subjects			
Hispanic/Latino	2	1	1
Non-Hispanic/non-Latino	3	0	0
Not reported	0	0	0

Reporting group values	Total		
Number of subjects	124		
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	102		
Adolescents (12-17 years)	15		
Adults (18-64 years)	5		
From 65-84 years	2		
85 years and over	0		
Age Continuous Units: years			
median			
full range (min-max)	-		
Gender Categorical Units: Subjects			
Female	51		
Male	73		
Race Units: Subjects			
White	104		
Black or African American	8		
Asian	3		
Multiracial	3		
Not reported	5		
American Indian or Alaska Native	1		
Ethinicity Units: Subjects			
Hispanic/Latino	24		
Non-Hispanic/non-Latino	99		
Not reported	1		

End points reporting groups

Reporting group title	2 to <5 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to < 5 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to < 5 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Non-Small Cell Lung Cancer

Reporting group description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>= 18 Years with Haemodialysis

Reporting group description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Primary: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV 2) Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV 2) Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[1][2]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 3

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[3]	0[4]	0[5]	
Units: Titers				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[3] - Results for this endpoint will be posted by March 2024.

[4] - Results for this endpoint will be posted by March 2024.

[5] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in

Subjects Aged >=5 to <12 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=5 to <12 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[6][7]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 3

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[8]	0[9]	0[10]	
Units: Titers				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[8] - Results for this endpoint will be posted by March 2024.

[9] - Results for this endpoint will be posted by March 2024.

[10] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[11][12]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 3

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[13]	0[14]	0[15]	
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[13] - Results for this endpoint will be posted by March 2024.

[14] - Results for this endpoint will be posted by March 2024.

[15] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 3 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[16][17]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 3 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 3

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[18]	0[19]	0[20]	
Units: Titers				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[18] - Results for this endpoint will be posted by March 2024.

[19] - Results for this endpoint will be posted by March 2024.

[20] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=2 to <5 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[21][22]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 4

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[23]	0[24]	0[25]	
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[23] - Results for this endpoint will be posted by March 2024.

[24] - Results for this endpoint will be posted by March 2024.

[25] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=5 to <12 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=5 to <12 Years Without

	Serological or Virological Evidence of Past SARS-CoV-2 Infection[26][27]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 4

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[28]	0[29]	0[30]	
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[28] - Results for this endpoint will be posted by March 2024.

[29] - Results for this endpoint will be posted by March 2024.

[30] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged 12 to <18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[31][32]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 4

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[33]	0[34]	0[35]	
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[33] - Results for this endpoint will be posted by March 2024.

[34] - Results for this endpoint will be posted by March 2024.

[35] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection

End point title	GMTs of SARSCoV2 Neutralizing Titers at 1 Month After Vaccination 4 in Subjects Aged >=18 Years Without Serological or Virological Evidence of Past SARS-CoV-2 Infection[36][37]

End point description:

GMT of SARS-CoV-2 neutralizing titers at 1 month after vaccination 4 in subjects without serological or virological evidence of past SARS-CoV-2 infection will be reported in this endpoint. Results for this endpoint will be posted by March 2024.

End point type	Primary

End point timeframe:

1 Month after Vaccination 4

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[38]	0[39]	0[40]	
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[38] - Results for this endpoint will be posted by March 2024.

[39] - Results for this endpoint will be posted by March 2024.

[40] - Results for this endpoint will be posted by March 2024.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years[41][42]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to 7 after vaccination.Redness and swelling were measured and recorded in measuring device units(mdu) where, 1 mdu =0.5 cm and were graded as mild(>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm),severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild(did not interfere with activity),moderate(interfered with activity),severe(prevented daily activity) and Grade 4(emergency room [ER] visit or hospitalisation for severe pain at injection site).Grade 4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination included.Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. Overall Number Analysed (N)= subjects evaluable for

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	13	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 24.7)	
Redness: Mild	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 24.7)	
Redness: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Redness: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Redness: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Swelling: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Swelling: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Swelling: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	

Swelling: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Swelling: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Pain at the injection site: Any	11.1 (0.3 to 48.2)	13.3 (1.7 to 40.5)	23.1 (5.0 to 53.8)	
Pain at the injection site: Mild	11.1 (0.3 to 48.2)	13.3 (1.7 to 40.5)	23.1 (5.0 to 53.8)	
Pain at the injection site: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Pain at the injection site: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Pain at the injection site: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=5 to <12 Years[43][44]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	10.5 (1.3 to 33.1)	8.3 (1.0 to 27.0)	9.1 (1.1 to 29.2)	
Redness: Mild	10.5 (1.3 to 33.1)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	

Redness: Moderate	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
Redness: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Redness: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Swelling: Any	5.3 (0.1 to 26.0)	4.2 (0.1 to 21.1)	18.2 (5.2 to 40.3)	
Swelling: Mild	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	13.6 (2.9 to 34.9)	
Swelling: Moderate	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
Swelling: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Swelling: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Pain at the injection site: Any	73.7 (48.8 to 90.9)	58.3 (36.6 to 77.9)	54.5 (32.2 to 75.6)	
Pain at the injection site: Mild	52.6 (28.9 to 75.6)	50.0 (29.1 to 70.9)	45.5 (24.4 to 67.8)	
Pain at the injection site: Moderate	21.1 (6.1 to 45.6)	8.3 (1.0 to 27.0)	9.1 (1.1 to 29.2)	
Pain at the injection site: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Pain at the injection site: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=12 to <18 Years[45][46]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	7	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Redness: Mild	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Redness: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Redness: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Redness: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Swelling: Any	28.6 (3.7 to 71.0)	100.0 (2.5 to 100.0)	14.3 (0.4 to 57.9)	
Swelling: Mild	0 (0.0 to 41.0)	100.0 (2.5 to 100.0)	0 (0.0 to 41.0)	
Swelling: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Swelling: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Swelling: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Pain at the injection site: Any	85.7 (42.1 to 99.6)	100.0 (2.5 to 100.0)	57.1 (18.4 to 90.1)	
Pain at the injection site: Mild	71.4 (29.0 to 96.3)	100.0 (2.5 to 100.0)	28.6 (3.7 to 71.0)	
Pain at the injection site: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Pain at the injection site: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Pain at the injection site: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=18 Years[47][48]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Pain at injection site: Any	80.0 (28.4 to 99.5)	100.0 (2.5 to 100.0)	100.0 (2.5 to 100.0)	
Pain at injection site: Mild	40.0 (5.3 to 85.3)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Pain at injection site: Moderate	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	100.0 (2.5 to 100.0)	
Pain at injection site: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Pain at injection site: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years[49][50]

End point description:

Local reactions collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm), severe(>7.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis[redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate(interfered with activity), severe(prevented daily activity),Grade 4(ER visit or hospitalisation for severe pain at injection site).Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention.' N'=

subjects evaluable for this endpoint. Number Analysed ('n')= subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	11	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any (n=9,15,10)	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Redness: Mild (n=9,15,10)	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Redness: Moderate (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Redness: Severe (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Redness: Grade 4 (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Swelling: Any (n=9,15,10)	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Swelling: Mild (n=9,15,10)	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Swelling: Moderate (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Swelling: Severe (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Swelling: Grade 4 (n=9,15,10)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Pain at injection site: Any (n=9,15,11)	11.1 (0.3 to 48.2)	20.0 (4.3 to 48.1)	9.1 (0.2 to 41.3)	
Pain at injection site: Mild (n=9,15,11)	11.1 (0.3 to 48.2)	20.0 (4.3 to 48.1)	9.1 (0.2 to 41.3)	
Pain at injection site: Moderate (n=9,15,11)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Pain at injection site: Severe (n=9,15,11)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Pain at injection site: Grade 4 (n=9,15,11)	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged

	>=5 to <12 Years[51][52]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	10.5 (1.3 to 33.1)	12.5 (2.7 to 32.4)	22.7 (7.8 to 45.4)	
Redness: Mild	10.5 (1.3 to 33.1)	4.2 (0.1 to 21.1)	13.6 (2.9 to 34.9)	
Redness: Moderate	0 (0.0 to 17.6)	8.3 (1.0 to 27.0)	9.1 (1.1 to 29.2)	
Redness: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Redness: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Swelling: Any	10.5 (1.3 to 33.1)	8.3 (1.0 to 27.0)	31.8 (13.9 to 54.9)	
Swelling: Mild	10.5 (1.3 to 33.1)	4.2 (0.1 to 21.1)	9.1 (1.1 to 29.2)	
Swelling: Moderate	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	22.7 (7.8 to 45.4)	
Swelling: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Swelling: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Pain at injection site: Any	68.4 (43.4 to 87.4)	62.5 (40.6 to 81.2)	50.0 (28.2 to 71.8)	
Pain at injection site: Mild	52.6 (28.9 to 75.6)	45.8 (25.6 to 67.2)	22.7 (7.8 to 45.4)	
Pain at injection site: Moderate	15.8 (3.4 to 39.6)	16.7 (4.7 to 37.4)	27.3 (10.7 to 50.2)	
Pain at injection site: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Pain at injection site: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=12 to <18 Years[53][54]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	6	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
Redness: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
Redness: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
Swelling: Mild	0 (0.0 to 41.0)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	

Swelling: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Pain at injection site: Any	85.7 (42.1 to 99.6)	100.0 (2.5 to 100.0)	57.1 (18.4 to 90.1)	
Pain at injection site: Mild	57.1 (18.4 to 90.1)	100.0 (2.5 to 100.0)	28.6 (3.7 to 71.0)	
Pain at injection site: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Pain at injection site: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Pain at injection site: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=18 Years[55][56]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Redness: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Redness: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Swelling: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Pain at injection site: Any	80.0 (28.4 to 99.5)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Pain at injection site: Mild	60.0 (14.7 to 94.7)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Pain at injection site: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Pain at injection site: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Pain at injection site: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=2 to <5 Years[57][58]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	11	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	11.1 (0.3 to 48.2)	13.3 (1.7 to 40.5)	0 (0.0 to 28.5)	
Redness: Mild	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Redness: Moderate	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Redness: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Redness: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Swelling: Any	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Swelling: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Swelling: Moderate	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Swelling: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Swelling: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Pain at injection site: Any	22.2 (2.8 to 60.0)	13.3 (1.7 to 40.5)	9.1 (0.2 to 41.3)	
Pain at injection site: Mild	0 (0.0 to 33.6)	13.3 (1.7 to 40.5)	9.1 (0.2 to 41.3)	
Pain at injection site: Moderate	22.2 (2.8 to 60.0)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Pain at injection site: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Pain at injection site: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=5 to <12 Years[59][60]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	23	21	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	29.4 (10.3 to 56.0)	4.3 (0.1 to 21.9)	14.3 (3.0 to 36.3)	
Redness: Mild	17.6 (3.8 to 43.4)	0 (0.0 to 14.8)	9.5 (1.2 to 30.4)	
Redness: Moderate	11.8 (1.5 to 36.4)	4.3 (0.1 to 21.9)	4.8 (0.1 to 23.8)	
Redness: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Redness: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Swelling: Any	17.6 (3.8 to 43.4)	8.7 (1.1 to 28.0)	14.3 (3.0 to 36.3)	
Swelling: Mild	5.9 (0.1 to 28.7)	0 (0.0 to 14.8)	9.5 (1.2 to 30.4)	
Swelling: Moderate	11.8 (1.5 to 36.4)	8.7 (1.1 to 28.0)	4.8 (0.1 to 23.8)	
Swelling: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Swelling: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Pain at injection site: Any	70.6 (44.0 to 89.7)	26.1 (10.2 to 48.4)	57.1 (34.0 to 78.2)	
Pain at injection site: Mild	35.3 (14.2 to 61.7)	21.7 (7.5 to 43.7)	42.9 (21.8 to 66.0)	
Pain at injection site: Moderate	35.3 (14.2 to 61.7)	4.3 (0.1 to 21.9)	14.3 (3.0 to 36.3)	
Pain at injection site: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Pain at injection site: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=12 to <18 Years[61][62]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm), moderate(>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4

(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate(interfered with activity), severe(prevented daily activity) and Grade 4(ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population= all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint. 'n'= subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	7	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any (n= 7,1,6)	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Mild (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Moderate (n= 7,1,6)	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Severe (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Redness: Grade 4 (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Any (n= 7,1,6)	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Mild (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Moderate (n= 7,1,6)	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Severe (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Swelling: Grade 4 (n= 7,1,6)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Pain at injection site: Any (n= 7,1,7)	71.4 (29.0 to 96.3)	100.0 (2.5 to 100.0)	66.7 (22.3 to 95.7)	
Pain at injection site: Mild (n= 7,1,7)	28.6 (3.7 to 71.0)	100.0 (2.5 to 100.0)	33.3 (4.3 to 77.7)	
Pain at injection site: Moderate (n= 7,1,7)	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Pain at injection site: Severe (n= 7,1,7)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Pain at injection site: Grade 4 (n= 7,1,7)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years[63][64]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[63] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	0[65]	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Redness: Mild	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Redness: Moderate	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Redness: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Redness: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Swelling: Any	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Swelling: Mild	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Swelling: Moderate	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Swelling: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Swelling: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Pain at injection site: Any	75.0 (19.4 to 99.4)	(to)	0 (0.0 to 97.5)	
Pain at injection site: Mild	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
Pain at injection site: Moderate	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Pain at injection site: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Pain at injection site: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	

Notes:

[65] - No subjects were evaluable for this endpoint from this arm.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=2 to <5 Years[66][67]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	6	6	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	28.6 (3.7 to 71.0)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Redness: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Redness: Moderate	14.3 (0.4 to 57.9)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Redness: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Redness: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Swelling: Any	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	

Swelling: Mild	0 (0.0 to 41.0)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	
Swelling: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Swelling: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Swelling: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Pain at injection site: Any	28.6 (3.7 to 71.0)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	
Pain at injection site: Mild	28.6 (3.7 to 71.0)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	
Pain at injection site: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Pain at injection site: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Pain at injection site: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=5 to <12 Years[68][69]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	15	
Units: Percentage of subjects				
number (confidence interval 95%)				

Redness: Any	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	20.0 (4.3 to 48.1)	
Redness: Mild	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	6.7 (0.2 to 31.9)	
Redness: Moderate	0 (0.0 to 26.5)	0 (0.0 to 17.6)	13.3 (1.7 to 40.5)	
Redness: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Redness: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Swelling: Any	16.7 (2.1 to 48.4)	5.3 (0.1 to 26.0)	20.0 (4.3 to 48.1)	
Swelling: Mild	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	13.3 (1.7 to 40.5)	
Swelling: Moderate	8.3 (0.2 to 38.5)	0 (0.0 to 17.6)	6.7 (0.2 to 31.9)	
Swelling: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Swelling: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Pain at injection site: Any	91.7 (61.5 to 99.8)	42.1 (20.3 to 66.5)	40.0 (16.3 to 67.7)	
Pain at injection site: Mild	41.7 (15.2 to 72.3)	31.6 (12.6 to 56.6)	26.7 (7.8 to 55.1)	
Pain at injection site: Moderate	50.0 (21.1 to 78.9)	10.5 (1.3 to 33.1)	13.3 (1.7 to 40.5)	
Pain at injection site: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Pain at injection site: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=12 to <18 Years[70][71]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	1	3	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	75.0 (19.4 to 99.4)	0 (0.0 to 97.5)	66.7 (9.4 to 99.2)	
Redness: Mild	75.0 (19.4 to 99.4)	0 (0.0 to 97.5)	66.7 (9.4 to 99.2)	
Redness: Moderate	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Redness: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Redness: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Swelling: Any	50.0 (6.8 to 93.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Swelling: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Swelling: Moderate	50.0 (6.8 to 93.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Swelling: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Swelling: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Pain at injection site: Any	75.0 (19.4 to 99.4)	100.0 (2.5 to 100.0)	33.3 (0.8 to 90.6)	
Pain at injection site: Mild	25.0 (19.4 to 99.4)	100.0 (2.5 to 100.0)	0 (0.0 to 70.8)	
Pain at injection site: Moderate	50.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Pain at injection site: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	
Pain at injection site: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Local Reactions by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years[72][73]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (greater than [>] 2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and Grade 4 (necrosis [swelling] or necrosis or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 (ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population = all subjects who received at least 1 dose of study intervention. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[72] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	0[74]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Redness: Mild	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Redness: Moderate	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Redness: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Redness: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Swelling: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Swelling: Mild	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Swelling: Moderate	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Swelling: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Swelling: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Pain at injection site: Any	66.7 (9.4 to 99.2)	100.0 (2.5 to 100.0)	(to)	
Pain at injection site: Mild	33.3 (0.8 to 90.6)	100.0 (2.5 to 100.0)	(to)	
Pain at injection site: Moderate	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Pain at injection site: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Pain at injection site: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	

Notes:

[74] - No subjects were evaluable for this endpoint from this arm.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=2 to <5 Years[75][76]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after vaccination. Fever:oral temperature >=) 38.0 degree C (C);categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 degree C.Fatigue, headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity), moderate (some interference with activity),severe (prevented daily routine activity).Vomiting: mild: 1-2 times in 24 hours,moderate: >2

times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours,moderate: 4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events:ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[75] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	13	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	15.4 (1.9 to 45.4)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	
Fever: >40.0 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Fatigue: Any	22.2 (2.8 to 60.0)	6.7 (0.2 to 31.9)	7.7 (0.2 to 36.0)	
Fatigue: Mild	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Fatigue: Moderate	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	7.7 (0.2 to 36.0)	
Fatigue: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Fatigue: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Headache: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Headache: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Headache: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Headache: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Headache: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Chills: Any	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	
Chills: Mild	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Chills: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	
Chills: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Chills: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Vomiting: Any	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	23.1 (5.0 to 53.8)	
Vomiting: Mild	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	

Vomiting: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	15.4 (1.9 to 45.4)	
Vomiting: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Vomiting: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Diarrhea: Any	0 (0.0 to 33.6)	20.0 (4.3 to 48.1)	7.7 (0.2 to 36.0)	
Diarrhea: Mild	0 (0.0 to 33.6)	20.0 (4.3 to 48.1)	0 (0.0 to 24.7)	
Diarrhea: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
Diarrhea: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	7.7 (0.2 to 36.0)	
Diarrhea: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened muscle pain: Any	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened muscle pain: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened muscle pain: Moderate	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened muscle pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened muscle pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened joint pain: Any	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened joint pain: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened joint pain: Moderate	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened joint pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	
New or worsened joint pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 24.7)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=5 to <12 Years[77][78]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[77] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[78] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fever: >40.0 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fatigue: Any	47.4 (24.4 to 71.1)	37.5 (18.8 to 59.4)	22.7 (7.8 to 45.4)	
Fatigue: Mild	31.6 (12.6 to 56.6)	20.8 (7.1 to 42.2)	13.6 (2.9 to 34.9)	
Fatigue: Moderate	15.8 (3.4 to 39.6)	16.7 (4.7 to 37.4)	9.1 (1.1 to 29.2)	
Fatigue: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fatigue: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Headache: Any	42.1 (20.3 to 66.5)	12.5 (2.7 to 32.4)	22.7 (7.8 to 45.4)	
Headache: Mild	31.6 (12.6 to 56.6)	12.5 (2.7 to 32.4)	9.1 (1.1 to 29.2)	
Headache: Moderate	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	13.6 (2.9 to 34.9)	
Headache: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Headache: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Chills: Any	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Chills: Mild	0 (0.0 to 17.6)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Chills: Moderate	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Chills: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Chills: Grade 4	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Vomiting: Any	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Mild	5.3 (0.1 to 26.0)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Vomiting: Moderate	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Diarrhea: Any	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Diarrhea: Mild	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Diarrhea: Moderate	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Diarrhea: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Diarrhea: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

New or worsened muscle pain: Any	5.3 (0.1 to 26.0)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
New or worsened muscle pain: Mild	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened muscle pain: Moderate	5.3 (0.1 to 26.0)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
New or worsened muscle pain: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened muscle pain: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Any	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Mild	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Moderate	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=12 to <18 Years[79][80]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[79] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	7	
Units: Percentage of subjects				
number (confidence interval 95%)				

Fever: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fever: >=38.0 deg C to 38.4 deg C	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fever: >38.4 deg C to 38.9 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fever: >40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fatigue: Any	57.1 (18.4 to 90.1)	0 (0.0 to 97.5)	42.9 (9.9 to 81.6)	
Fatigue: Mild	0 (0.0 to 41.0)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Fatigue: Moderate	57.1 (18.4 to 90.1)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Fatigue: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Fatigue: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Headache: Any	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Headache: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Headache: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	
Headache: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Headache: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Chills: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Chills: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Chills: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Chills: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Chills: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Vomiting: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Vomiting: Mild	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Vomiting: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Vomiting: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Vomiting: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Diarrhea: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Diarrhea: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	28.6 (3.7 to 71.0)	
Diarrhea: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Diarrhea: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
Diarrhea: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened muscle pain: Any	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	42.9 (9.9 to 81.6)	
New or worsened muscle pain: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	42.9 (9.9 to 81.6)	
New or worsened muscle pain: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened muscle pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened muscle pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened joint pain: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened joint pain: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened joint pain: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	
New or worsened joint pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	

New or worsened joint pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 1 in Subjects Aged >=18 Years[81][82]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 1

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >=38 to 38.4 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >40.0 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Any	60.0 (14.7 to 94.7)	100.0 (2.5 to 100.0)	100.0 (2.5 to 100.0)	
Fatigue: Mild	40.0 (5.3 to 85.3)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Fatigue: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	100.0 (2.5 to 100.0)	

Fatigue: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Any	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	100.0 (2.5 to 100.0)	
Headache: Mild	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	100.0 (2.5 to 100.0)	
Headache: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Grade 4	0 (0.0 to 85.3)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Any	40.0 (5.3 to 85.3)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Diarrhea: Mild	40.0 (5.3 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Moderate	0 (0.0 to 52.2)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Diarrhea: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Any	20.0 (0.5 to 71.6)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
New or worsened muscle pain: Mild	0 (0.0 to 52.2)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
New or worsened muscle pain: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Any	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=2 to <5 Years[83][84]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[83] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	10	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fever: >=38.0 deg C to 38.4 deg C	11.1 (0.3 to 48.2)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fever: >38.4 deg C to 38.9 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fever: >40.0 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fatigue: Any	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	10.0 (0.3 to 44.5)	
Fatigue: Mild	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	10.0 (0.3 to 44.5)	
Fatigue: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fatigue: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Fatigue: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Headache: Any	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Headache: Mild	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 30.8)	
Headache: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Headache: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Headache: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Chills: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Chills: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Chills: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Chills: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Chills: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	

Vomiting: Any	0 (0.0 to 33.6)	13.3 (1.7 to 40.5)	10.0 (0.3 to 44.5)	
Vomiting: Mild	0 (0.0 to 33.6)	13.3 (1.7 to 40.5)	0 (0.0 to 30.8)	
Vomiting: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	10.0 (0.3 to 44.5)	
Vomiting: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Vomiting: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Diarrhea: Any	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	10.0 (0.3 to 44.5)	
Diarrhea: Mild	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	10.0 (0.3 to 44.5)	
Diarrhea: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Diarrhea: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
Diarrhea: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened muscle pain: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened muscle pain: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened muscle pain: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened muscle pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened muscle pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened joint pain: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened joint pain: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 30.8)	
New or worsened joint pain: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=5 to <12 Years[85][86]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[85] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Fever: >=38.0 deg C to 38.4 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fever: >38.4 deg C to 38.9 deg C	5.3 (0.1 to 26.0)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fever: >40.0 deg C	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fatigue: Any	57.9 (33.5 to 79.7)	37.5 (18.8 to 59.4)	45.5 (24.4 to 67.8)	
Fatigue: Mild	26.3 (9.1 to 51.2)	20.8 (7.1 to 42.2)	13.6 (2.9 to 34.9)	
Fatigue: Moderate	31.6 (12.6 to 56.6)	16.7 (4.7 to 37.4)	31.8 (13.9 to 54.9)	
Fatigue: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Fatigue: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Headache: Any	36.8 (16.3 to 61.6)	29.2 (12.6 to 51.1)	18.2 (5.2 to 40.3)	
Headache: Mild	15.8 (3.4 to 39.6)	12.5 (2.7 to 32.4)	4.5 (0.1 to 22.8)	
Headache: Moderate	21.1 (6.1 to 45.6)	16.7 (4.7 to 37.4)	13.6 (2.9 to 34.9)	
Headache: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Headache: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Chills: Any	21.1 (6.1 to 45.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
Chills: Mild	10.5 (1.3 to 33.1)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Chills: Moderate	10.5 (1.3 to 33.1)	0 (0.0 to 14.2)	4.5 (0.1 to 22.8)	
Chills: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Chills: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Any	0 (0.0 to 17.6)	12.5 (2.7 to 32.4)	0 (0.0 to 15.4)	
Vomiting: Mild	0 (0.0 to 17.6)	12.5 (2.7 to 32.4)	0 (0.0 to 15.4)	
Vomiting: Moderate	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Vomiting: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Diarrhea: Any	5.3 (0.1 to 26.0)	8.3 (1.0 to 27.0)	4.5 (0.1 to 22.8)	
Diarrhea: Mild	5.3 (0.1 to 26.0)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
Diarrhea: Moderate	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
Diarrhea: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
Diarrhea: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

New or worsened muscle pain: Any	10.5 (1.3 to 33.1)	12.5 (2.7 to 32.4)	4.5 (0.1 to 22.8)	
New or worsened muscle pain: Mild	0 (0.0 to 17.6)	4.2 (0.1 to 21.1)	0 (0.0 to 15.4)	
New or worsened muscle pain: Moderate	10.5 (1.3 to 33.1)	8.3 (1.0 to 27.0)	4.5 (0.1 to 22.8)	
New or worsened muscle pain: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened muscle pain: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Any	15.8 (3.4 to 39.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
New or worsened joint pain: Mild	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Moderate	15.8 (3.4 to 39.6)	4.2 (0.1 to 21.1)	4.5 (0.1 to 22.8)	
New or worsened joint pain: Severe	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	
New or worsened joint pain: Grade 4	0 (0.0 to 17.6)	0 (0.0 to 14.2)	0 (0.0 to 15.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=12 to <18 Years[87][88]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[87] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	6	
Units: Percentage of subjects				

number (confidence interval 95%)				
Fever: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >=38.0 deg C to 38.4 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >38.4 deg C to 38.9 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >38.9 deg C to 40.0 deg C	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Any	85.7 (42.1 to 99.6)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Fatigue: Mild	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Fatigue: Moderate	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Severe	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Headache: Any	71.4 (29.0 to 96.3)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
Headache: Mild	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
Headache: Moderate	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Headache: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Headache: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Any	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Mild	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened muscle pain: Any	42.9 (9.9 to 81.6)	100.0 (2.5 to 100.0)	16.7 (0.4 to 64.1)	
New or worsened muscle pain: Mild	0 (0.0 to 41.0)	100.0 (2.5 to 100.0)	0 (0.0 to 45.9)	
New or worsened muscle pain: Moderate	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
New or worsened muscle pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened muscle pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	

New or worsened joint pain: Mild	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 2 in Subjects Aged >=18 Years[89][90]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 2

Notes:

[89] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >=38.0 to 38.4 deg C	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >40.0 deg C	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Any	60.0 (14.7 to 94.7)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	

Fatigue: Mild	0 (0.0 to 52.2)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Fatigue: Moderate	60.0 (14.7 to 94.7)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Any	60.0 (14.7 to 94.7)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Headache: Mild	20.0 (0.5 to 71.6)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Headache: Moderate	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Any	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Moderate	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Any	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Moderate	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Any	60.0 (14.7 to 94.7)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Diarrhea: Mild	40.0 (5.3 to 85.3)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Moderate	20.0 (0.5 to 71.6)	100.0 (2.5 to 100.0)	0 (0.0 to 97.5)	
Diarrhea: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Any	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Any	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Mild	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Moderate	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Severe	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity

Within 7 Days After Vaccination 3 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=2 to <5 Years[91][92]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[91] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	11	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Fever: >=38.0 deg C to 38.4 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Fever: >38.4 deg C to 38.9 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Fever: >40.0 deg C	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Fatigue: Any	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Fatigue: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Fatigue: Moderate	11.1 (0.3 to 48.2)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Fatigue: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Fatigue: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Headache: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Headache: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Headache: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Headache: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Headache: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Chills: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Chills: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Chills: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	

Chills: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Chills: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Vomiting: Any	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Vomiting: Mild	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
Vomiting: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Vomiting: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Vomiting: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Diarrhea: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Diarrhea: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Diarrhea: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Diarrhea: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
Diarrhea: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened muscle pain: Any	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
New or worsened muscle pain: Mild	0 (0.0 to 33.6)	6.7 (0.2 to 31.9)	0 (0.0 to 28.5)	
New or worsened muscle pain: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened muscle pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened muscle pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Any	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Mild	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Moderate	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=5 to <12 Years[93][94]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[93] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[94] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	23	21	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	17.6 (3.8 to 43.4)	0 (0.0 to 14.8)	19.0 (5.4 to 41.9)	
Fever: >=38.0 to 38.4 deg C	11.8 (1.5 to 36.4)	0 (0.0 to 14.8)	14.3 (3.0 to 36.3)	
Fever: >38.4°C to 38.9 deg C	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Fever: >38.9°C to 40.0 deg C	0 (0.0 to 19.5)	0 (0.0 to 14.8)	4.8 (0.1 to 23.8)	
Fever: >40.0 deg C	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Fever: Unknown	5.9 (0.1 to 28.7)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Fatigue: Any	47.1 (23.0 to 72.2)	34.8 (16.4 to 57.3)	52.4 (47.2 to 74.3)	
Fatigue: Mild	35.3 (14.2 to 61.7)	34.8 (16.4 to 57.3)	23.8 (8.2 to 47.2)	
Fatigue: Moderate	11.8 (1.5 to 36.4)	21.7 (7.5 to 43.7)	28.6 (11.3 to 52.2)	
Fatigue: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Fatigue: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Headache: Any	35.3 (14.2 to 61.7)	8.7 (1.1 to 28.0)	28.6 (11.3 to 52.2)	
Headache: Mild	29.4 (10.3 to 56.0)	4.3 (0.1 to 21.9)	9.5 (1.2 to 30.4)	
Headache: Moderate	5.9 (0.1 to 28.7)	0 (0.0 to 14.8)	19.0 (5.4 to 41.9)	
Headache: Severe	0 (0.0 to 19.5)	4.3 (0.1 to 21.9)	0 (0.0 to 16.1)	
Headache: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Chills: Any	17.6 (3.8 to 43.4)	4.3 (0.1 to 21.9)	14.3 (3.0 to 36.3)	
Chills: Mild	5.9 (0.1 to 28.7)	4.3 (0.1 to 21.9)	4.8 (0.1 to 23.8)	
Chills: Moderate	11.8 (1.5 to 36.4)	0 (0.0 to 14.8)	9.5 (3.0 to 36.3)	
Chills: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Chills: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Vomiting: Any	0 (0.0 to 19.5)	0 (0.0 to 14.8)	4.8 (0.1 to 23.8)	
Vomiting: Mild	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Vomiting: Moderate	0 (0.0 to 19.5)	0 (0.0 to 14.8)	4.8 (0.1 to 23.8)	
Vomiting: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	

Vomiting: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Diarrhea: Any	11.8 (1.5 to 36.4)	0 (0.0 to 14.8)	4.8 (0.1 to 23.8)	
Diarrhea: Mild	11.8 (1.5 to 36.4)	0 (0.0 to 14.8)	4.8 (0.1 to 23.8)	
Diarrhea: Moderate	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Diarrhea: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
Diarrhea: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened muscle pain: Any	29.4 (10.3 to 56.0)	13.0 (2.8 to 33.6)	4.8 (0.1 to 23.8)	
New or worsened muscle pain: Mild	5.9 (0.1 to 28.7)	13.0 (2.8 to 33.6)	4.8 (0.1 to 23.8)	
New or worsened muscle pain: Moderate	23.5 (6.8 to 49.9)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened muscle pain: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened muscle pain: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened joint pain: Any	11.8 (1.5 to 36.4)	4.3 (2.8 to 33.6)	4.8 (0.1 to 23.8)	
New or worsened joint pain: Mild	0 (0.0 to 19.5)	4.3 (2.8 to 33.6)	4.8 (0.1 to 23.8)	
New or worsened joint pain: Moderate	11.8 (1.5 to 36.4)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened joint pain: Severe	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	
New or worsened joint pain: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 14.8)	0 (0.0 to 16.1)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=12 to <18 Years[95][96]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[95] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	6	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	42.9 (9.9 to 81.6)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Fever: >=38.0 to 38.4 deg C	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Fever: >38.4°C to 38.9 deg C	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >38.9°C to 40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fever: >40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Any	85.7 (42.1 to 99.6)	100.0 (2.5 to 100.0)	50.0 (11.8 to 88.2)	
Fatigue: Mild	14.3 (0.4 to 57.9)	100.0 (2.5 to 100.0)	50.0 (11.8 to 88.2)	
Fatigue: Moderate	71.4 (29.0 to 96.3)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Fatigue: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Headache: Any	85.7 (42.1 to 99.6)	100.0 (2.5 to 100.0)	66.7 (22.3 to 95.7)	
Headache: Mild	28.6 (3.7 to 71.0)	100.0 (2.5 to 100.0)	33.3 (4.3 to 77.7)	
Headache: Moderate	57.1 (18.4 to 90.1)	0 (0.0 to 97.5)	33.3 (4.3 to 77.7)	
Headache: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Headache: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Any	71.4 (29.0 to 96.3)	100.0 (2.5 to 100.0)	16.7 (0.4 to 64.1)	
Chills: Mild	14.3 (0.4 to 57.9)	100.0 (2.5 to 100.0)	16.7 (0.4 to 64.1)	
Chills: Moderate	57.1 (18.4 to 90.1)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Chills: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Any	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Mild	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Vomiting: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Moderate	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
Diarrhea: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened muscle pain: Any	28.6 (3.7 to 71.0)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
New or worsened muscle pain: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	
New or worsened muscle pain: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	

New or worsened muscle pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened muscle pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Any	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Mild	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	
New or worsened joint pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 3 in Subjects Aged >=18 Years[97][98]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 3

Notes:

[97] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[98] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	0[99]	1	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever:Any	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	

Fever: >40.0 deg C	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Fatigue: Any	75.0 (19.4 to 99.4)	(to)	0 (0.0 to 97.5)	
Fatigue: Mild	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
Fatigue: Moderate	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Fatigue: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Fatigue: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Headache: Any	75.0 (19.4 to 99.4)	(to)	0 (0.0 to 97.5)	
Headache: Mild	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Headache: Moderate	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
Headache: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Headache: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Chills: Any	50.0 (0.6 to 93.2)	(to)	0 (0.0 to 97.5)	
Chills: Mild	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Chills: Moderate	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Chills: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Chills: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Vomiting: Any	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Vomiting: Mild	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Vomiting: Moderate	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Vomiting: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Vomiting: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Diarrhea: Any	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Diarrhea: Mild	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Diarrhea: Moderate	25.0 (0.6 to 80.6)	(to)	0 (0.0 to 97.5)	
Diarrhea: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
Diarrhea: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened muscle pain: Any	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
New or worsened muscle pain: Mild	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened muscle pain: Moderate	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
New or worsened muscle pain: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened muscle pain: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened joint pain: Any	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
New or worsened joint pain: Mild	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened joint pain: Moderate	50.0 (6.8 to 93.2)	(to)	0 (0.0 to 97.5)	
New or worsened joint pain: Severe	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 60.2)	(to)	0 (0.0 to 97.5)	

Notes:

[99] - No subjects were evaluable for this endpoint from this arm.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=2 to <5 Years[100][101]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration .Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[100] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[101] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	6	6	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	28.6 (3.7 to 71.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fever: >=38.0 to 38.4 deg C	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fever: >38.4 to 38.9 deg C	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fever: >40.0 deg C	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fatigue: Any	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	
Fatigue: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	
Fatigue: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fatigue: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Fatigue: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Headache: Any	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Headache: Mild	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Headache: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Headache: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	

Headache: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Chills: Any	14.3 (0.4 to 57.9)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Chills: Mild	0 (0.0 to 41.0)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Chills: Moderate	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Chills: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Chills: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Vomiting: Any	0 (0.0 to 41.0)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Vomiting: Mild	0 (0.0 to 41.0)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	
Vomiting: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Vomiting: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Vomiting: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Diarrhea: Any	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Diarrhea: Mild	14.3 (0.4 to 57.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Diarrhea: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Diarrhea: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
Diarrhea: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened muscle pain: Any	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened muscle pain: Mild	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened muscle pain: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened muscle pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened muscle pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened joint pain: Any	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened joint pain: Mild	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened joint pain: Moderate	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened joint pain: Severe	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	
New or worsened joint pain: Grade 4	0 (0.0 to 41.0)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=5 to <12 Years[102][103]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever:oral temperature >= 38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 degree C. Fatigue, headache,chills,new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate(some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration. Diarrhea:mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours. Grade 4 for all events:ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[102] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[103] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	15	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	6.7 (0.2 to 31.9)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Fever: >38.9 to 40.0 deg C	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	6.7 (0.2 to 31.9)	
Fever: >40.0 deg C	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Fatigue: Any	50.0 (21.1 to 78.9)	26.3 (9.1 to 51.2)	33.3 (11.8 to 61.6)	
Fatigue: Mild	33.3 (9.9 to 65.1)	10.5 (1.3 to 33.1)	13.3 (1.7 to 40.5)	
Fatigue: Moderate	16.7 (2.1 to 48.4)	15.8 (3.4 to 39.6)	20.0 (4.3 to 48.1)	
Fatigue: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Fatigue: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Headache: Any	33.3 (9.9 to 65.1)	21.1 (6.1 to 45.6)	13.3 (1.7 to 40.5)	
Headache: Mild	8.3 (0.2 to 38.5)	15.8 (3.4 to 39.6)	0 (0.0 to 21.8)	
Headache: Moderate	25.0 (5.5 to 57.2)	5.3 (0.1 to 26.0)	6.7 (0.2 to 31.9)	
Headache: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	6.7 (0.2 to 31.9)	
Headache: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Chills: Any	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	13.3 (1.7 to 40.5)	
Chills: Mild	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	0 (0.0 to 21.8)	
Chills: Moderate	0 (0.0 to 26.5)	0 (0.0 to 17.6)	13.3 (1.7 to 40.5)	
Chills: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Chills: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Vomiting: Any	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	0 (0.0 to 21.8)	
Vomiting: Mild	8.3 (0.2 to 38.5)	5.3 (0.1 to 26.0)	0 (0.0 to 21.8)	
Vomiting: Moderate	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Vomiting: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	

Vomiting: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Diarrhea: Any	25.0 (5.5 to 57.2)	15.8 (3.4 to 39.6)	6.7 (0.2 to 31.9)	
Diarrhea: Mild	25.0 (5.5 to 57.2)	10.5 (1.3 to 33.1)	6.7 (0.2 to 31.9)	
Diarrhea: Moderate	0 (0.0 to 26.5)	5.3 (0.1 to 26.0)	0 (0.0 to 21.8)	
Diarrhea: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
Diarrhea: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
New or worsened muscle pain: Any	16.7 (2.1 to 48.4)	15.8 (3.4 to 39.6)	6.7 (0.2 to 31.9)	
New or worsened muscle pain: Mild	0 (0.0 to 26.5)	15.8 (3.4 to 39.6)	0 (0.0 to 21.8)	
New or worsened muscle pain: Moderate	8.3 (0.2 to 38.5)	0 (0.0 to 17.6)	6.7 (0.2 to 31.9)	
New or worsened muscle pain: Severe	8.3 (0.2 to 38.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
New or worsened muscle pain: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
New or worsened joint pain: Any	25.0 (5.5 to 57.2)	0 (0.0 to 17.6)	6.7 (0.2 to 31.9)	
New or worsened joint pain: Mild	8.3 (0.2 to 38.5)	0 (0.0 to 17.6)	6.7 (0.2 to 31.9)	
New or worsened joint pain: Moderate	16.7 (2.1 to 48.4)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
New or worsened joint pain: Severe	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	
New or worsened joint pain: Grade 4	0 (0.0 to 26.5)	0 (0.0 to 17.6)	0 (0.0 to 21.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=12 to <18 Years[104][105]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination.Fever: oral temperature >=38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 degree C. Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe:required intravenous hydration:Diarrhea:mild: 2-3 loose stools in 24 hours,moderate: 4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. 'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[104] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	1	3	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >38.4 to 38.9 deg C	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Fever: >38.9 to 40.0 deg C	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fever: >40.0 deg C	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Any	50.0 (6.8 to 93.2)	100.0 (2.5 to 100.0)	66.7 (9.4 to 99.2)	
Fatigue: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Fatigue: Moderate	50.0 (6.8 to 93.2)	100.0 (2.5 to 100.0)	33.3 (0.8 to 90.6)	
Fatigue: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Fatigue: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Any	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Headache: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Moderate	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Headache: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Headache: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Any	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Chills: Mild	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Chills: Moderate	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Chills: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Any	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Vomiting: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Vomiting: Moderate	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Vomiting: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Any	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Diarrhea: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Moderate	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
Diarrhea: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
Diarrhea: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Any	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	

New or worsened muscle pain: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Moderate	25.0 (0.6 to 80.6)	0 (0.0 to 97.5)	33.3 (0.8 to 90.6)	
New or worsened muscle pain: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened muscle pain: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Any	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Mild	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Moderate	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Severe	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	
New or worsened joint pain: Grade 4	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting Systemic Events by Maximum Severity Within 7 Days After Vaccination 4 in Subjects Aged >=18 Years[106][107]

End point description:

Systemic events were recorded in e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after vaccination. Fever: oral temperature >=38.0 C;categorised as >=38.0 to 38.4 C, >38.4 to 38.9 C, >38.9 to 40.0 C and >40.0 C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain: mild (did not interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe:6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population.'N'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Vaccination 4

Notes:

[106] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[107] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	0[108]	
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: Any	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Fever: >38.4 to 38.9 deg C	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	

Fever: >38.9 to 40.0 deg C	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Fever: >40.0 deg C	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Fatigue: Any	66.7 (9.4 to 99.2)	0 (0.0 to 97.5)	(to)	
Fatigue: Mild	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Fatigue: Moderate	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Fatigue: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Fatigue: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Headache: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Headache: Mild	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Headache: Moderate	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Headache: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Headache: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Chills: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Chills: Mild	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Chills: Moderate	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
Chills: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Chills: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Vomiting: Any	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Vomiting: Mild	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Vomiting: Moderate	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Vomiting: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Vomiting: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Diarrhea: Any	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Diarrhea: Mild	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Diarrhea: Moderate	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Diarrhea: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
Diarrhea: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened muscle pain: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
New or worsened muscle pain: Mild	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened muscle pain: Moderate	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
New or worsened muscle pain: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened muscle pain: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened joint pain: Any	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
New or worsened joint pain: Mild	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened joint pain: Moderate	33.3 (0.8 to 90.6)	0 (0.0 to 97.5)	(to)	
New or worsened joint pain: Severe	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	
New or worsened joint pain: Grade 4	0 (0.0 to 70.8)	0 (0.0 to 97.5)	(to)	

Notes:

[108] - No subjects were evaluable for this endpoint from this arm.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=2 to <5 Years[109][110]

End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 1 month after Vaccination 2

Notes:

[109] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	13	
Units: Percentage of subjects				
number (confidence interval 95%)	44.4 (13.7 to 78.8)	33.3 (11.8 to 61.6)	38.5 (13.9 to 68.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=5 to <12 Years[111][112]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 1 month after Vaccination 2

Notes:

[111] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[112] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)	36.8 (16.3 to 61.6)	8.3 (1.0 to 27.0)	27.3 (0.7 to 50.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=5 to <12 Years[113][114]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[113] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[114] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	23	22	
Units: Percentage of subjects				
number (confidence interval 95%)	29.4 (10.3 to	8.7 (1.1 to	4.5 (0.1 to	

56.0)	28.0)	22.8)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=2 to <5 Years[115][116]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[115] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[116] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	11	
Units: Percentage of subjects				
number (confidence interval 95%)	33.3 (7.5 to 70.1)	40.0 (16.3 to 67.7)	0 (0.0 to 28.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=12 to <18 Years[117][118]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 1 month after Vaccination 2

Notes:

[117] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[118] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	7	
Units: Percentage of subjects				
number (confidence interval 95%)	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	14.3 (0.4 to 57.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 1 to 1 Month After Vaccination 2 in Subjects Aged >=18 Years[119][120]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 1 to 1 month after vaccination 2 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 1 month after Vaccination 2

Notes:

[119] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[120] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=18 Years[121][122]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[121] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.

[122] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 52.2)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=2 to <5 Years[123][124]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[123] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	6	6	
Units: Percentage of subjects				
number (confidence interval 95%)	14.3 (0.4 to 57.9)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=5 to <12 Years[125][126]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[125] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[126] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	15	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 26.5)	36.8 (16.3 to 61.6)	0 (0.0 to 21.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 3 to 1 Month After Vaccination 3 in Subjects Aged >=12 to <18 Years[127][128]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 3 to 1 month after vaccination 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 3 to 1 month after Vaccination 3

Notes:

[127] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[128] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	6	
Units: Percentage of subjects				
number (confidence interval 95%)	14.3 (0.4 to 57.9)	0 (0.0 to 97.5)	16.7 (0.4 to 64.1)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged >=5 to <12 Years

End point title	Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged >=5 to <12 Years[129][130]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[129] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[130] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	5 to <12 Years with Immunomodulatory Therapy	5 to <12 Years with Solid Organ Transplant	5 to <12 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	22	
Units: Percentage of subjects				
number (confidence interval 95%)	15.8 (3.4 to 39.6)	20.8 (7.1 to 42.2)	13.6 (2.9 to 34.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event From Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=12 to <18 Years[131][132]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[131] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[132] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	1	3	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 60.2)	0 (0.0 to 97.5)	0 (0.0 to 70.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Serious Adverse Events (SAEs) From Vaccination 1 Through the Duration of the Study in Subjects Aged >=2 to <5 Years

End point title	Percentage of Subjects Reporting Serious Adverse Events (SAEs) From Vaccination 1 Through the Duration of the Study in Subjects Aged >=2 to <5 Years[133][134]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[133] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[134] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	2 to <5 Years with Immunomodulatory Therapy	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	15	13	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 33.6)	53.3 (26.6 to 78.7)	23.1 (5.0 to 53.8)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting at Least 1 Adverse Event After Vaccination 4 to 1 Month After Vaccination 4 in Subjects Aged >=18 Years[135][136]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of subjects reporting AEs after vaccination 4 to 1 month after vaccination 4 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 4 to 1 month after Vaccination 4

Notes:

[135] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[136] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	0[137]	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 70.8)	100.0 (2.5 to	(to)	

	100.0)

Notes:

[137] - No subjects were evaluable for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting SAEs From Dose 1 Through the Duration of the Study in Subjects Aged >=18 Years

End point title	Percentage of Subjects Reporting SAEs From Dose 1 Through the Duration of the Study in Subjects Aged >=18 Years[138][139]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[138] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[139] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	1	1	
Units: Percentage of subjects				
number (confidence interval 95%)	20.0 (0.5 to 71.6)	0 (0.0 to 97.5)	100.0 (2.5 to 100.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged >=12 to <18 Years

End point title	Percentage of Subjects Reporting SAEs From Vaccination 1 Through the Duration of the Study in Subjects Aged >=12 to <18 Years[140][141]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, and other situations as medical judgement of investigator. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all subjects who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Vaccination 1 to 6 month after Vaccination 4 (approximately 14 months)

Notes:

[140] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms. No statistical analyses were planned for this primary endpoint.
[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	7	
Units: Percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 41.0)	0 (0.0 to 97.5)	0 (0.0 to 41.0)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events up to Day 7 each dose. AEs were reported from first dose of study treatment up to 1 month after last dose of study treatment (approximately 9 months). For SAE, from Dose 1 to 6 month after Dose 4 (approximately 14 months).

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but are distinct events. An event may be categorised as serious in 1 subject and non-serious in another, or a subject may have experienced both SAE and non-SAE.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	2 to < 5 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 2 to <5 years who had solid organ transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to < 5 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 2 to <5 years who had stem cell transplant were administered four doses of 3 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 5 to <12 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 5 to <12 years who had solid organ transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	2 to <5 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 2 to <5 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 3 microgram (mcg) of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	5 to <12 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 5 to <12 years who had stem cell transplant were administered four doses of 10 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged 12 to <18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Solid Organ Transplant

Reporting group description:

Subjects aged 12 to <18 years who had solid organ transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	12 to <18 Years with Stem Cell Transplant

Reporting group description:

Subjects aged 12 to <18 years who had stem cell transplant were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Immunomodulatory Therapy

Reporting group description:

Subjects aged >=18 years receiving immunomodulator therapy for an autoimmune inflammatory disorder were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>=18 Years with Non-Small Cell Lung Cancer

Reporting group description:

Subjects with non-small cell lung cancer aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Reporting group title	>= 18 Years with Haemodialysis

Reporting group description:

Subjects undergone maintenance haemodialysis treatment aged >=18 years were administered four doses of 30 mcg of BNT162b2 intramuscularly. The first 2 doses were separated by 21 days, the third dose was administered 28 days after Dose 2 and fourth dose was administered 3 to 6 months after Dose 3.

Serious adverse events	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	5 to <12 Years with Immunomodulatory Therapy
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 15 (53.33%)	3 / 13 (23.08%)	3 / 19 (15.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheter removal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Influenza like illness			

subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney transplant rejection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary vein stenosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			

subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 15 (0.00%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal colic			

subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 15 (13.33%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gangrene			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	5 to <12 Years with Solid Organ Transplant	2 to <5 Years with Immunomodulatory Therapy	5 to <12 Years with Stem Cell Transplant
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 24 (20.83%)	0 / 9 (0.00%)	3 / 22 (13.64%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheter removal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney transplant rejection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary vein stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheter removal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney transplant rejection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary vein stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dental caries			

subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Myositis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheter removal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney transplant rejection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary vein stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal colic			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gangrene			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	2 to < 5 Years with Solid Organ Transplant	2 to < 5 Years with Stem Cell Transplant	5 to <12 Years with Immunomodulatory Therapy
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 15 (86.67%)	10 / 13 (76.92%)	18 / 19 (94.74%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to bone			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 15 (20.00%)	3 / 13 (23.08%)	14 / 19 (73.68%)
occurrences (all)	3	3	34
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 15 (20.00%)	0 / 13 (0.00%)	7 / 19 (36.84%)
occurrences (all)	5	0	10
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	1 / 13 (7.69%)	7 / 19 (36.84%)
occurrences (all)	1	1	9
Chills			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Medical device site inflammation			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			

subjects affected / exposed	3 / 15 (20.00%)	4 / 13 (30.77%)	16 / 19 (84.21%)
occurrences (all)	6	4	50
Injection site pain			
subjects affected / exposed	1 / 15 (6.67%)	1 / 13 (7.69%)	1 / 19 (5.26%)
occurrences (all)	1	2	1
Injection site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	2 / 13 (15.38%)	2 / 19 (10.53%)
occurrences (all)	1	2	4
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	1 / 13 (7.69%)	5 / 19 (26.32%)
occurrences (all)	2	1	8
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Breast pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood iron decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Donor specific antibody present			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Foreign body in eye			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Tumour necrosis factor receptor-associated periodic syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nervous system disorders			

Headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	11 / 19 (57.89%)
occurrences (all)	1	0	25
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Lymphadenitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye disorders			
Amblyopia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Eye inflammation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 13 (7.69%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Eye discharge			

subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Photophobia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Uveitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Crohn's disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 15 (20.00%)	4 / 13 (30.77%)	2 / 19 (10.53%)
occurrences (all)	4	4	2
Vomiting			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 15 (20.00%)	2 / 13 (15.38%)	5 / 19 (26.32%)
occurrences (all)	4	2	8
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Purpura			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	6 / 19 (31.58%)
occurrences (all)	1	0	10
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	4 / 19 (21.05%)
occurrences (all)	0	0	10
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile colitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dengue fever			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	1 / 15 (6.67%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Epstein-Barr viraemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Stoma site cellulitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Otitis externa			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	3 / 15 (20.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Tooth infection			

subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Viral sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	5 to <12 Years with Solid Organ Transplant	2 to <5 Years with Immunomodulatory Therapy	5 to <12 Years with Stem Cell Transplant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 24 (95.83%)	8 / 9 (88.89%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to bone			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 24 (70.83%)	3 / 9 (33.33%)	14 / 22 (63.64%)
occurrences (all)	31	4	31
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 24 (20.83%)	3 / 9 (33.33%)	6 / 22 (27.27%)
occurrences (all)	7	4	13
Chills (CHILLS)			

alternative assessment type: Systematic			
subjects affected / exposed	3 / 24 (12.50%)	2 / 9 (22.22%)	5 / 22 (22.73%)
occurrences (all)	3	2	7
Chills			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Medical device site inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	18 / 24 (75.00%)	4 / 9 (44.44%)	19 / 22 (86.36%)
occurrences (all)	43	6	40
Injection site pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Injection site erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 24 (8.33%)	2 / 9 (22.22%)	5 / 22 (22.73%)
occurrences (all)	2	3	6
Swelling (SWELLING)			
alternative assessment type: Systematic			

subjects affected / exposed	4 / 24 (16.67%)	1 / 9 (11.11%)	8 / 22 (36.36%)
occurrences (all)	6	2	17
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Donor specific antibody present			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Foreign body in eye			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Tumour necrosis factor receptor-associated periodic syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 24 (45.83%)	0 / 9 (0.00%)	9 / 22 (40.91%)
occurrences (all)	16	0	17
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			

subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amblyopia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Ocular discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			

Abdominal pain upper			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	2 / 24 (8.33%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Gastritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 24 (16.67%)	1 / 9 (11.11%)	1 / 22 (4.55%)
occurrences (all)	5	1	1
Vomiting			
subjects affected / exposed	2 / 24 (8.33%)	1 / 9 (11.11%)	2 / 22 (9.09%)
occurrences (all)	2	1	2
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 24 (20.83%)	2 / 9 (22.22%)	2 / 22 (9.09%)
occurrences (all)	5	2	4
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 24 (4.17%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Rash erythematous			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 24 (33.33%)	1 / 9 (11.11%)	3 / 22 (13.64%)
occurrences (all)	10	1	3
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 24 (8.33%)	1 / 9 (11.11%)	3 / 22 (13.64%)
occurrences (all)	2	1	3
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Clostridium difficile colitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr viraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Stoma site cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Otitis media chronic			
subjects affected / exposed	1 / 24 (4.17%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Otitis media			

subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	3 / 24 (12.50%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 24 (12.50%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	6	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 9 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Viral sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Viral rhinitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 24 (0.00%)	1 / 9 (11.11%)	0 / 22 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	12 to <18 Years with Immunomodulatory Therapy	12 to <18 Years with Solid Organ Transplant	12 to <18 Years with Stem Cell Transplant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	1 / 1 (100.00%)	6 / 7 (85.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to bone			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 7 (85.71%)	1 / 1 (100.00%)	5 / 7 (71.43%)
occurrences (all)	18	2	10
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	7	0	4
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 7 (71.43%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	10	1	2
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Medical device site inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type:			

Systematic			
subjects affected / exposed	6 / 7 (85.71%)	1 / 1 (100.00%)	5 / 7 (71.43%)
occurrences (all)	20	4	12
Injection site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences (all)	7	0	3
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 7 (28.57%)	1 / 1 (100.00%)	2 / 7 (28.57%)
occurrences (all)	8	1	3
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Donor specific antibody present			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foreign body in eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Tumour necrosis factor receptor-associated periodic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	4
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 7 (100.00%)	1 / 1 (100.00%)	6 / 7 (85.71%)
occurrences (all)	15	1	8
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amblyopia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye discharge			

subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 7 (28.57%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	5
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	9	1	6
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 7 (28.57%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr viraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	>=18 Years with Immunomodulatory Therapy	>=18 Years with Non-Small Cell Lung Cancer	>= 18 Years with Haemodialysis
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to bone			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 5 (80.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	11	2	1
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Chills (CHILLS)			

alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	5	0	1
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Medical device site inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 5 (80.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	13	3	1
Injection site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Swelling (SWELLING)			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Breast enlargement			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Donor specific antibody present			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Foreign body in eye			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Tumour necrosis factor receptor-associated periodic syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 5 (80.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	9	1	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amblyopia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 5 (60.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	6	2	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Myalgia (NEW OR WORSENED MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Arthralgia (NEW OR WORSENED JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stoma site cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis media			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Tracheitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Viral sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 June 2021	Amendment 1: Updated section 2.3- Added safety text indicating that no specific safety concerns were identified by subgroup analysis by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.
05 August 2021	Amendment 2: Updated Section 2.3.1– Risk Assessment for subjects, Updated section 3: Added primary and exploratory safety, tolerability, and immune response objectives for the expanded cohort of subjects on active immunomodulator therapy.
21 January 2022	Amendment 4: Reduced the Visit 5 window for provision of Dose 3; Clarified that if Visit 4 and Visit 5 occur on the same day, duplicate procedures need not be conducted; Updated procedures to allow vaccination with the age-appropriate dose removed; immunogenicity blood collection at Visit 5 and Visit 6; Removed PBMC collection at Visit 5 and Visit 7.
13 January 2023	Amendment 5: Updated Sections 1.1 - Number of subjects in each group based on actual recruitment figures; Updated Sections 8.9.8, 8.9.9, 8.9.10: clarifying the requirements for study procedures after protocol amendment 4.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported